Remarks

This Amendment is in response to the Office Action dated **March 17, 2009.**

Rejections

35 U.S.C. §102(b)

The rejection of claims 1-9, 13-24 under 35 U.S.C. § 102(b) as being anticipated by WO 01/78906 (Spillman) has been maintained.

Applicants traverse the rejection.

It is asserted in the Office Action that:

> Spillman discloses an alternating thin film of alternating charge Further, nanoclusters of Zr02, Al203 or Ti02 are also disclosed. This film may be used to coat catheters, stents and similar medical devices (see Abstract). Charged polymers are found at page 5 lines 1-11 and include fullerenes and nanotubes. Ceramic particles disclosed at page 8, lines 12-13. Alternative layering is disclosed at pages 9-10. Nanoclusters are disclosed at page 12, lines 19-29, The size of the layers is disclosed as between about 0.1 to 100 nm (page 13, lines 12-15). Multilayered forms are disclosed at page 13, line 5; page 15, lines 18-25; clams 74 and 75; and Figured 10 (ad). A bioactive is included in the invention at claim 15; [0068] — [0075] for specific bioactives. The instant claims are anticipated by Spillman.
>
> Office Action, page 3

Claim 1 was previously amended to recite a medical device comprising a multilayer region that comprises a charged nanoparticle layer comprising charged nanoparticles, a plurality of charged polyelectroyte layers comprising charged polyelectrolyte species, and *at least one charged therapeutic agent,* wherein said medical device is configured for implantation or insertion into a subject.

Applicants submit that the claim limitation of "at least one charged therapeutic agent" has not been sufficiently addressed in the Office Action to maintain a rejection under 35

U.S.C. §102(b).

While it is true that claim 15 of Spillman (WO 01/78906) does recite "a substrate made biocompatible by a process according to claim 1 *and at least one drug*", there is no disclosure as to any specific "drugs" disclosed by Spillman, much less any disclosure or suggestion to employ a "charged therapeutic agent" as recited in claim 1. See paragraph [0043].

Therapeutic agents are not inherently charged. There is no explanation in the Office Action as to how Spillman anticipates the addition of a "charged therapeutic agent" wherein the therapeutic agent itself is charged, or it is intimately associated with a charged molecule. See paragraph [0043].

Spillman fails to anticipate claim 1 because there is no disclosure or suggestion in Spillman to employ a charged therapeutic agent. "Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. §102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim." *Net MoneyIN Inc. v. VeriSign Inc.*, 88 USPQ2D 1751, 1758 (Fed. Cir. 2008) (cites omitted).

Claims 2-9 and 13-24 depend from claim 1 and are not anticipated by Spillman (WO 01/78906) for at least the reasons that claim 1 is not anticipated by Spillman.

Withdrawal of the rejection of claims 1-9, 13-24 under 35 U.S.C. § 102(b) as being anticipated by WO 01/78906 (Spillman) is respectfully requested.

35 U.S.C. §112

Claim 56 has been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is asserted that:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
>
> Support could not be found for the fibrous reinforcement member" of claim 56. Clarification is requested.
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> Office Action, pages 3-4

Please refer to paragraph [0063]. Clearly, "fibrous reinforcement member" is supported by the specification.

Withdrawal of the rejection of claim 56 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Allowable Subject Matter

Claims 10-12 and 25-30 have been indicated as being allowable.

For at least the reasons set forth above, claims 1-9, 11-30 and 53-57 are patentably distinct over the art of record.

However, for purposes of expediting prosecution, Applicants have also added new claims 58-60 incorporating limitations from claims 10, 11, 25, 26, 28 and 29.

Claim 58 incorporates the limitations of claims 1, 10 and 11. Spillman fails to disclose or suggest a protective coating over the multilayer region.

Claim 59 incorporates the limitations of claims 1, 25 and 26. Spillman fails to disclose or suggest fiber reinforcement adjacent to or within the multilayer region in the form of a

fiber mesh, fiber braid, or fiber winding.

Claim 60 incorporates the limitations of claims 1, 28 and 29. Spillman fails to disclose or suggest charged nanocapsules incorporated into the multilayer region that comprise a therapeutic agent.

CONCLUSION

Claims 1-9, 11-30 and 53-60 are pending in the application. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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